VitaScan LT

USB Ultrasound Bladder Monitor

User and Service Manual

Version 4.5.2.

Date: 09 *November 2012.*

The Information contained in this user and service manual is proprietary to Vitacon. It is only used for convenience of our customers. It may be changed in whole or in part without written notice. Any service work performed by persons who are not authorized by Vitacon may void your warranty.

Disclaimer

Vitacon provides this publication as is without warranty of any kind, either express or implied, including but not limited to the implied warranties of merchantability or fitness for any particular purpose. Further, Vitacon reserves the right to revise this publication and to make changes from time to time to the content hereof, without obligation to Vitacon or its local representatives to notify any person of such revision or changes. Some jurisdictions do not allow disclaimers of expressed or implied warranties in certain transactions; therefore, this statement may not apply to you.

Limited Warranty

Vitacon warrants that the VitaScan LT USB Ultrasound Bladder Monitor will substantially conform to published specifications and to the documentation, provided that it is used for the purpose for which it was designed. Vitacon will, for a period of twelve (12) months from date of purchase, replace or repair any defective device, if the fault is due to a manufacturing defect. In no event will Vitacon or its local representatives be liable for direct, indirect, special, incidental, or consequential damages arising out of the use of or inability to use the VitaScan LT USB Ultrasound Bladder Monitor, even if advised of the possibility of such damages. Vitacon or its local representatives are not responsible for any costs, loss of profits, loss of data, or claims by third parties due to use of, or inability to use the VitaScan LT USB Ultrasound Bladder Monitor. Neither Vitacon nor its local representatives will accept, nor be bound by any other form of guarantee concerning the VitaScan LT USB Ultrasound Bladder Monitor other than this guarantee. Some jurisdictions do not allow disclaimers of expressed or implied warranties in certain transactions; therefore, this statement may not apply to you.

Contacting Vitacon

In Europe :
Vitacon AS
Vegamot 8
N-7048 Trondheim
Norway
http://www.vitacon.com
E-mail: sales@vitacon.com

In North America :
Vitacon Medical Inc.
5355 Parkwood Place
Richmond, BC V6V 2N1
Canada
E-mail: na.sales@vitacon.com

or

Vitacon US
5563 Pioneer Creek Drive
Maple Plane, Minnesota 55359
USA
E-mail: info@vitacon.us

Copyright 2012. All rights reserved.
PN: 6100-500

Tables of Contents

Introduction 4
Important Information 4
Indications for Use 5
Product Features 5
Unpacking and Inspection 5
Content of the packaging: 6
Storage 6
Technical Specifications 6
Product Upgrades and Updates 7
About the Ultrasound System 7
About the System Software 7
Electrical Safety 8
Equipment Safety 9
Safety and Performance Summary 9
Labeling Symbols 10
Applicable Standards/Approvals 10
Applying the Ultrasound Gel 11
Measuring Bladder Volume 12
Regular Inspections and Maintenance 12
Care, Cleaning and Disinfecting 13
VitaScan LT Application Software Installation 14
System Requirements 14
Installation of the VitaScan LT application 14
USB driver Installation 17
User Guide 20
PC Software Application Key Features 20
Application Features 20
Run VitaScan LT application 21
Scanning on Vitacon Phantom 24
Other settings 25
Application – Troubleshooting 26
Warranty and Disclaimer Information 27
Service 28

Introduction

VitaScan LT USB - Ultrasound Bladder Monitor

Real-time bladder scanning is a safe and easy, non-invasive method to measure bladder volume. Bladder scanning measures ultrasonic reflections within a patient's body and differentiates the urinary bladder from the surrounding tissues.

The VitaScan LT is a B-mode ultrasonic instrument, portable and battery operated, intended for the non-invasive measurement of urinary bladder volume. A mechanical sector scanning transducer provides cross-sectional images of the bladder from up to twenty four scan planes. Based on these images the VitaScan LT automatically calculates the estimated bladder volume in milliliters and displays it on a screen.

VitaScan LT is applicable in many clinical areas to determine bladder volume, time for bladder emptying and detection of post void residual volume (PVR).

A real-time image of the bladder during pre-scan makes it easier to detect the bladder before scanning.

Important Information

Notice To All Operators:
The VitaScan LT should be used only by individuals who have been trained and authorized by a physician or the institution providing patient care. All operators should read this manual prior to using the VitaScan LT. Failure to comply with these instructions may compromise the performance of the instrument and the safety of the patient.

Biological Safety:
To date, exposure to pulsed diagnostic ultrasound has not been shown to produce adverse physiological effects. However, ultrasound should be used only by a medical professionals when clinically indicated, using the lowest exposure times possible commensurate with clinical utility.

The ultrasonic output power of the VitaScan LT is not user-adjustable and is limited to the minimum level necessary for effective performance. Data on acoustic output levels can be found in the section titled, "Technical Specifications" in this manual.

It is recommended that users read the *Health Canada Guidelines for the Safe Use of Diagnostic Ultrasound* before using this, or any other diagnostic ultrasonic device. (http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/radiation/01hecs-secs255/01hecs-secs255-eng.pdf , note this link may change over time).

Statement of Intended Use:
The VitaScan LT projects ultrasound energy through the lower abdomen of the patient to obtain an image of the bladder. This image is used to determine bladder volume noninvasively.

Contraindications
The VitaScan LT is not intended for fetal use or pregnant patients.

⚠ **Warning:** Exposure of low power diagnostic ultrasound has not been shown to produce adverse effects. However, medical professionals should use ultrasound only when clinically indicated.

⚠ **Warning:** There is the hazard of possible explosion if the VitaScan LT instrument is used in the presence of flammable anesthetics.

First Time Users:
We advise new operators to use the VitaScan LT on patients with moderately full bladders, rather than initially attempting to locate nearly empty bladders.

⚠ Caution:

The VitaScan LT should not be used on a patient with open skin or wounds in the suprapubic region.

- The patient should not have a catheter in his/her bladder. This could affect the accuracy of the measurement.
- User care with suprapubic/pelvic surgery patients, Scar tissue, incisions, sutures and staples affect ultrasound transmission and reflection.
- Accuracy may be affected for patients with ascites or free floating fluid in the peritoneum.

Indications for Use

This manual is directed toward the reader who is familiar with Ultrasound techniques. Sonography training and clinical procedures are not included here. This manual is not intended as training material for the principles of ultrasound, anatomy, scanning techniques, or applications. You should be familiar with all of these before attempting to read this manual or using the device.

Product Features

- Real-time Ultrasound Bladder Scanner.
- 3D ultrasound scanner & PC running Windows XP/ Windows Vista/ Windows 7 OS
- USB ultrasound probe connection
- Bladder volume calculations in large digits
- Storage of ultrasound images

Unpacking and Inspection

There are no special unpacking instructions, but be careful not to damage the instrument when unpacking it. When unpacking the VitaScan LT to check for damage during shipment:

- Inspect the shipping carton for damage. If the shipping carton is damaged, carefully continue unpacking the instrument and note any dents and scratches on the VitaScan LT. Save the damaged shipping carton and packing material for the carrier's inspection and contact the respective carrier. If there is any damage on the scanner equipment, contact Vitacon.
- If there is no shipping damage, continue removing the VitaScan LT from the shipping case. Save the box and packing materials; they will be needed when returning the VitaScan LT to Vitacon for recalibration or future service.
- Verify that all items listed on the packing list have been received and are in good condition.

Note:

This box contains specifically designed foam inserts to ensure safe shipment of the VitaScan LT. Save these for future shipment of the unit for service or calibration.

Content of the packaging:

- VitaScan LT probe
- USB Memory stick with Application Software and User & Service Manual
- VitaScan LT probe holder
- Installation guide in English

Storage

If the system is to be stored, pack it in the original container, and keep it in an environment free of corrosive material, fluctuations in temperature and humidity, and vibration and shock.

Storage Requirements:
Storage temperature from -30°C to 50°C
Relative humidity of 20% to 90% @ 30°C, non-condensing
Atmospheric pressure from 700 hPa to 1060 hPa

As with most electronic equipment, the unit should be operated in a dry area within normal temperature limits (+10°C to +45°C, 10% - 80% humidity).

Dispose electronic waste:
VitaScan LT complies with the WEEE Directive (2002/96/EC) marking requirements. The affixed label indicates that you must not discard this Medical Electric Equipment in domestic household waste. Product category: With reference to the equipment types in WEEE directive annex IA, this product is classed as category 8 “Medical Devices”. To return unwanted products, contact Vitacon at the address mentioned at the front of this manual or your local VitaScan distributor.

Technical Specifications

Volume range:	0 – 1000 ml
Accuracy [1]:	+/- 10 % of reading, +/- 20 ml
Frequency:	2.35 MHz
Acoustic Output – MI max:	0.26 (Limit: 1.9)
Thermal Index – TI	< 0.02
Scanning method:	Sector, 180 degrees
Rotation positions:	6, 12 or 24 rotating positions
Sweep angle:	110 degrees
Max detection depth:	100, 160 or 230 mm
Max probe temperature:	35°C @ 22°C ambient temperature
Dimension	(L x W x H) 14 x 4.5 x 6.6 cm (5.5 x 1.8 x 2.6 in.)
Weight incl. cable:	0.38kg (0.84lb)
IP rating:	IPX1
Power Supplied by	USB port
Operating conditions:	+10°C to + 25°C, 10 % - 80 % relative humidity
Storage temperature:	-30°C to +50°C
PC requirements:	Windows XP/ Vista/7 OS
PC Input method:	mouse, keyboard and touchscreen

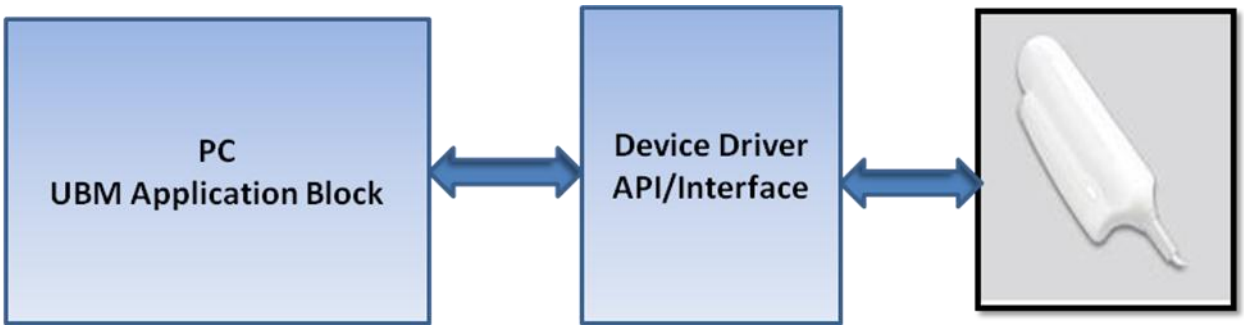
[1] Accuracy referred to measurements on Vitacon Phantoms only.

Product Upgrades and Updates

Vitacon may offer software upgrades and new features that may improve system performance. User and Service Manual updates, explaining the effects of upgrades and new features on system performance, will accompany the upgrades.

About the Ultrasound System

The VitaScan LT System includes: USB Probe, Laptop and a Medical Isolation transformer. For electrical safety reasons you should always power the Laptop from a Medical Isolating device.



VitaScan LT System

Number	Features	Specification
1	USB Scanner	VitaScan LT
2	Laptop/Computer	Dell XPS M1530 Model 9928L, or equivalent
3	Medical Isolation Transformer	Tripp Lite IS250HG or equivalent if mains operated
4	Software version 4.5.0 or higher	VitaScan LT
5	USB Memory stick With Software & Documentation	

About the System Software

The VitaScan LT system contains software that controls its operation.

Vitacon will provide you with a USB Memory stick containing the software. Typically new software provides new capabilities.

Electrical Safety

This system meets EN60601-1, Class I and Type BF isolated patient-applied parts safety requirements. This system complies with the applicable medical equipment requirements published in the European Norm Harmonized Standards, Underwriters Laboratories (UL) and the Canadian Standards Association (CSA).

For maximum safety observe the following warnings and cautions:

⚠ Warning:
To avoid the risk of electrical shock or injury, do not open the system enclosure.
All internal replacements must be made by a qualified technician.

To avoid the risk of injury, do not operate the system in the presence of flammable gasses or anesthetics.

To avoid the risk of electrical shock, use only properly grounded equipment.
Shock hazards exist if the power supply is not properly grounded. Grounding reliability can only be achieved when equipment is connected to a receptacle marked “Hospital Only” or “Hospital Grade” or the equivalent. The grounding wire must not be removed or defeated. Run Laptop on battery (internal electrical source) whenever integrity of the external protective earth conductor arrangement is in doubt.

To avoid the risk of electrical shock, before using the VitaScan LT, inspect the housing and USB cable. Do not use the VitaScan LT if these are damaged.

To avoid the risk of electrical shock, always disconnect the USB Cable from the PC before cleaning the system.

To avoid the risk of electrical shock, do not use any transducer that has been accidentally immersed in any liquid, or has been immersed in any liquid for cleaning or any other purpose.

To avoid the risk of electrical shock, do not touch Laptop/Computer output connector (like USB port and others) and the patient at the same time.

Caution:
Although your system has been manufactured in compliance with existing EMC/EMI requirements (EN60601-1-2), use of the system in the presence of an electromagnetic field can cause degradation of the ultrasound image. If this occurs often, Vitacon Bladder Monitor suggests a review of the system environment. Identify and remove the possible sources of the emissions or move your system.

Medical Electric Equipment can be affected by portable or mobile RF communication devices. Turn OFF any portable or mobile RF device before operating your system.

Electrostatic discharge (ESD), or static shock, is a naturally occurring phenomenon. ESD is common in conditions of low humidity, which can be caused by heating or air conditioning.

Static shock is a discharge of electrical energy from a charged body to a lesser or non-charged body. The degree of discharge can be significant enough to cause damage to a transducer or an ultrasound system. The following precautions can help reduce ESD: anti-static spray on carpets, anti-static spray on linoleum, and anti-static mats.

Do not use the system if an error message appears on the display: note the error code; call Vitacon or your local representative; turn off the system.

Equipment Safety

To protect your ultrasound system, scanner, and accessories, follows these precautions.

Caution:

- Use a Medical Isolation Device to power the Laptop.
- To avoid the risk of excessive heating or damage to the system, use the system in a well ventilated environment.
- If the operating environmental temperature exceeds 25°C, limit scans to 5 minutes and allow a 10 minute cooling period between scans.
- Excessive bending or twisting of cables can cause a failure or intermittent operation.
- Do not submerge the VitaScan LT in any solution, follow the cleaning instructions.
- To avoid damaging the power supply, verify the power supply input is within the correct voltage range.
- Do not short the battery terminals.
- Always charge the Laptop battery before using the system, to avoid the risk of the system turning off while in use.
- Incorrect cleaning or disinfecting of any part of the system can cause permanent damage.
- Do not use solvents such as thinner or benzene, or abrasive cleaners on any part of the system.
- Do not spill liquid on the system.
- Do not use the system if it exhibits erratic or inconsistent behaviour. Turn Off the power of the system and call Customer Service Representative.
- Do not dispose of the battery in fire.
- Immediately discontinue use of the battery if, while using, charging or storing the battery, the battery emits an unusual smell, feels hot, changes colour or shape, or appears abnormal in any other way. Contact customer service representative if any of these problems are observed.
- Do not use the VitaScan LT if its head or cable is damaged.
- Do not use the VitaScan LT if there is evidence of leakage of internal liquids. Wash hands immediately in warm, soapy water. Consult the MSDS on Polypropylene Glycol for additional information/precautions.
- To avoid the risk of electrical shock, do not use any VitaScan LT that has been immersed in liquid.

Safety and Performance Summary

The VitaScan LT computes the volume of the urinary bladder based upon twenty four cross-sectional ultrasound images (or less). For maximum accuracy, be sure to hold the Scan head motionless while scanning.

The most accurate measurements are obtained when the patient rests quietly in the supine position.

Accuracy is compromised if the user does not obtain an optimal, repeatable image.

Errors in usage tend to result in the underestimation of bladder volume, except in cases where the Scan head is moved during scanning. In this case, the measurement may overestimate the patient's bladder volume.

The patient being scanned should not have a catheter in his/her bladder. This could create micro bubbles in the bladder, which affect the accuracy of the measurement.

Do not use the VitaScan LT on patients with open skin or wounds in the suprapubic region.

Use care when scanning suprapubic and pelvic surgery patients. Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and reflection.

⚠ **Warning:**
There is the possible hazard of explosion if the VitaScan LT is used in the presence of flammable anesthetics.

Labeling Symbols

CE mark – Notified body no.

Test Agency Certification Mark – North America

BF type (Body Floating)

WEEE - Waste Electrical and Electronic Equipment

Warning, consult accompanying documents

Read the documentation

Ultrasound radiation

Drip proof

Applicable Standards/Approvals

The Vitascan LT Bladder Monitor conforms with the following standards:

CSA C22.2 NO 60601-1-08: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1 Medical Electrical Equipment - Part 1: General requirements for safety, 1988: A1 1991-11, A2 1995

CSA C22.2 NO. 60601-1-2A-03 (R2006) [EN 60601-1-2 (2001) + A1 (2006)]: Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests

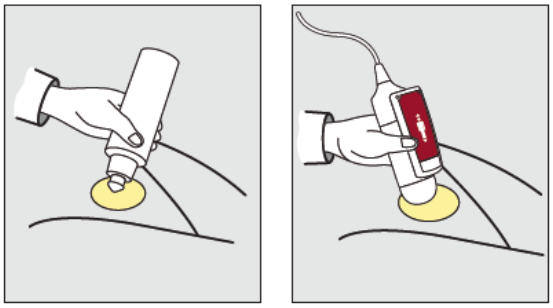
IEC 60601-2-37, Medical Electrical Equipment, Part 2-37: Particular Requirements for the basic safety and essential performance of ultrasonic equipment, Ed. 2.0, 2007-08

ISO 14971:2007 Medical devices – Application of risk management to medical devices

US FDA 510(k) market approval: K121689

Applying the Ultrasound Gel

Palpate the patient's symphysis pubis (pubic bone) and apply the Gel immediately superior to the patient's symphysis pubis, as shown in images below. Or apply the Gel around the dome of the Scanhead. Smooth the gel out and remove any air bubbles, which may block ultrasound transmission.

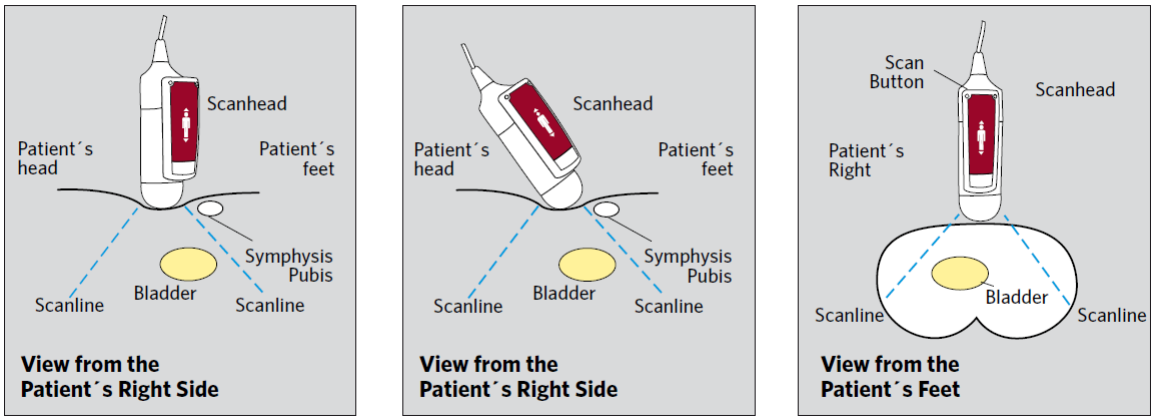


Using Ultrasound Gel Pad:
Sometimes it may be convenient to use ultrasound transmission Gel pad. The Gel pad is an easy-to-use coupling medium.

To apply the ultrasound Gel Pad, peel back the foil lid of the individual gel pad package, exposing the gel pad.

Measuring Bladder Volume

Palpate the patient's symphysis pubis and place the Scanhead midline on the patient's abdomen, approximately 4 cm (1.5 inches) superior to the symphysis pubis, as shown in images below.



- Aim the Scan head so the ultrasound is projected toward the expected location of the bladder. For most patients, this means aiming the tip of the Scanhead toward the patient's coccyx.
- Press and release the scan button, located on the Scanhead.
- Locate the bladder.
- Press and release the scan button and hold the Scanhead steady throughout the scan.

Note:
While scanning, avoid making any changes in the position, angle or pressure of the Scanhead.

Regular Inspections and Maintenance

VitaScan LT is a Medical Electric Equipment and therefore needs special precautions regarding EMC. VitaScan LT needs to be installed and put into service according to the EMC information provided in the accompanying documents.

Vitacon recommends that the VitaScan LT be certified by an authorized VitaScan LT Service Center once a year. Certification service includes a comprehensive inspection and testing of the instrument, to ensure accurate measurement performance. For more information, please contact your VitaScan LT Service Center Or your local VitaScan distributor.

Weekly Inspections:

Once a week, you should inspect the Scanhead and cable for physical faults or cracks. Cracks that allow the leakage or ingress of fluid may affect the safety and/or the performance of the instrument. Any apparent faults or cracks must be referred to your authorized VitaScan Service Center or your local VitaScan distributor.

Monthly Accuracy Check:

Caution:
In the event of changes in the performance of the instrument, discontinue use and contact your authorized VitaScan LT Service Center or your local VitaScan LT distributor.

Each month, or whenever accuracy assessment is desired or in question, the accuracy of the VitaScan LT should be tested using the following procedure:

- Take a Pre-void measurement of bladder volume.
- Void or catheterize into a measuring beaker.
- Take a post-void measurement of bladder volume to check for post-void residual (PVR)
- Subtract the post-void measurement form the pre-void measurement and compare to the voided volume.
- The measure volume should be within a range of ± 20%, ± 20ml of the voided volume.

Or

- Take a measurement on a Vitacon Phantom.
- The measure volume should be within a range of ± 10% of reading, +/- 20 ml

12 month Regular Inspection and Maintenance:

Vitacon recommends that the VitaScan LT to be certified by an authorized VitaScan LT service center once a year. Certification includes comprehensive inspection and testing of the instruments to ensure accurate performance in clinical use.

Customers can maintain device certification via Internet by accessing the VitaScan online integrity and filed calibration services. For more information contact your local dealer.

Care, Cleaning and Disinfecting

Clean the VitaScan LT with a soft cloth soaked in a mild liquid detergent solution. Rinse with clean water and carefully dry with a clean soft cloth. Dampen a soft cloth with 70% ethanol. Wipe the probe with the dampened soft cloth and let the ethanol evaporate.

If the VitaScan LT needs to be disinfected, dampen a soft cloth in any glutaraldehyde based hospital disinfection solution. (Use appropriate hand protection to avoid skin reactions with the glutaraldehyde.) Wipe the instrument with the dampened cloth. To remove all traces of disinfection solution, wipe the VitaScan LT with a clean soft cloth dampened in sterile water or cleaning solution. Carefully dry the VitaScan LT with a clean soft cloth before use.

⚠ **Warning**

- Do not subject any part of the VitaScan LT to steam sterilization or ethylene oxide sterilization.
- Do not immerse the instrument in any cleaning or disinfecting solution.
- Do not use CidexPlus® to disinfect the instrument. CidexPlus® may damage the plastic enclosure.

VitaScan LT Application Software Installation

Before use on patient:

Read the User Manual which is on the USB Memory stick, and follow user instruction for the scan-procedure.

System Requirements

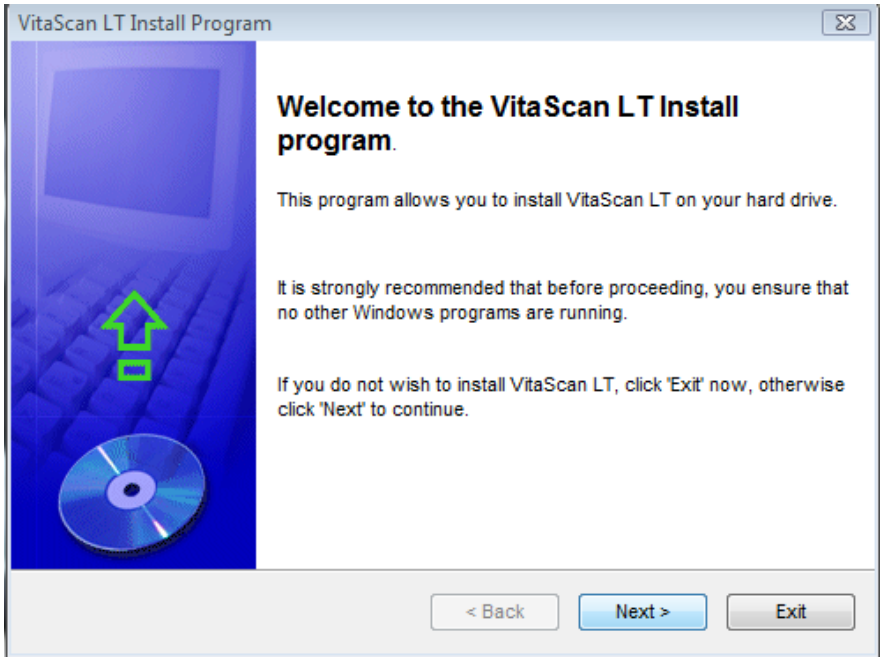
- Windows XP / Windows Vista / Windows 7 Operating System, 32 or 64 bit.
- The minimum recommended system configuration is 1GB RAM & 1.3 GHz processor speed.
- VitaScan LT USB Probe (Firmware version 2.7 or higher)
- Laptop/Computer type: Dell XPS M1530 Model 9928L, or equivalent
- USB 2.0 port to source 500mA @ 5V
- Medical Isolation Device – e.g. Tripp Lite IS150HG (N/A) or Noratel IMEDe 150 (Int'l)

Note: Installing VitaScan LT Application Software on Windows 7 Operating System requires operator logged in as "Administrator", and User Account set to "No Warning - when installing new software". Please read Windows 7 User Manual. Short instruction of User Account Setting:

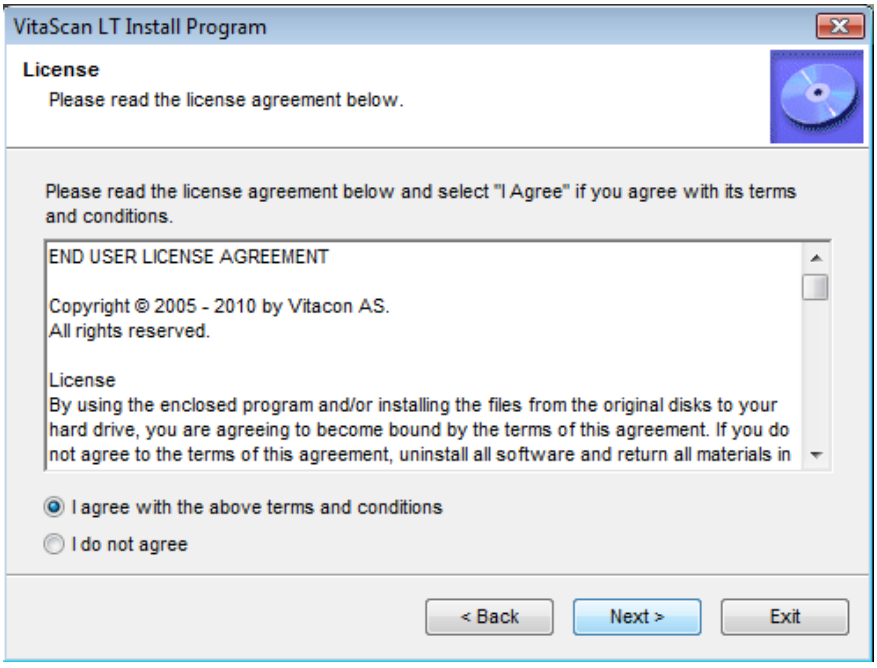
- Open "Control Panel"
- Select "User Accounts"
- Select "Change Settings"
- Drag the selection bar down to "No Warning"

Installation of the VitaScan LT application

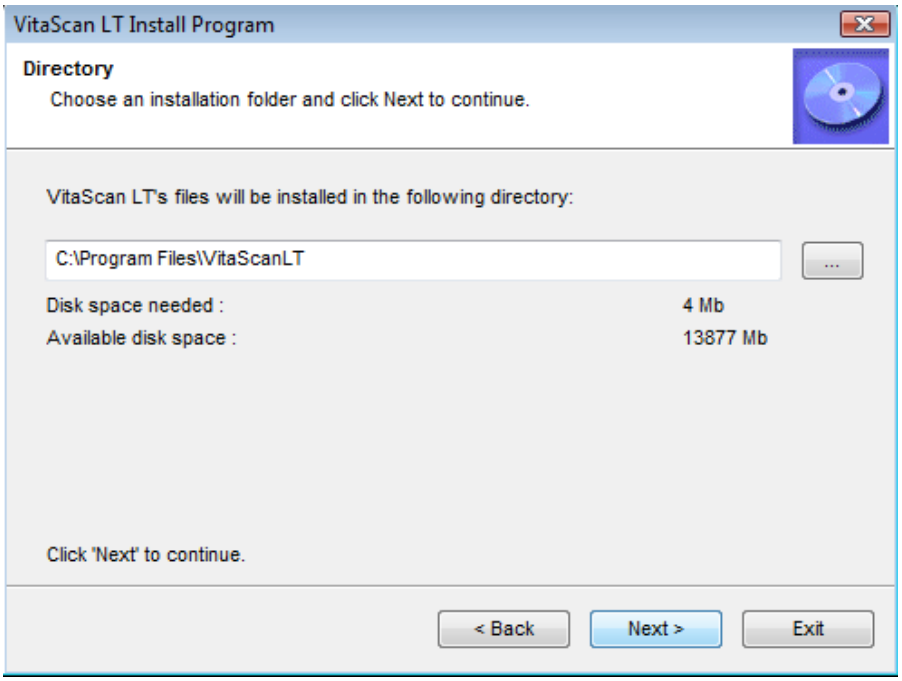
- Open the folder to view the "VitaScan_LT_Installer" files on the USB Memory stick
- Run the VitaScan_LT_Installer.exe file
- Press Next.


VitaScan LT Install Program
Welcome to the VitaScan LT Install program.
This program allows you to install VitaScan LT on your hard drive.
It is strongly recommended that before proceeding, you ensure that no other Windows programs are running.
If you do not wish to install VitaScan LT, click 'Exit' now, otherwise click 'Next' to continue.
< Back
Next >
Exit

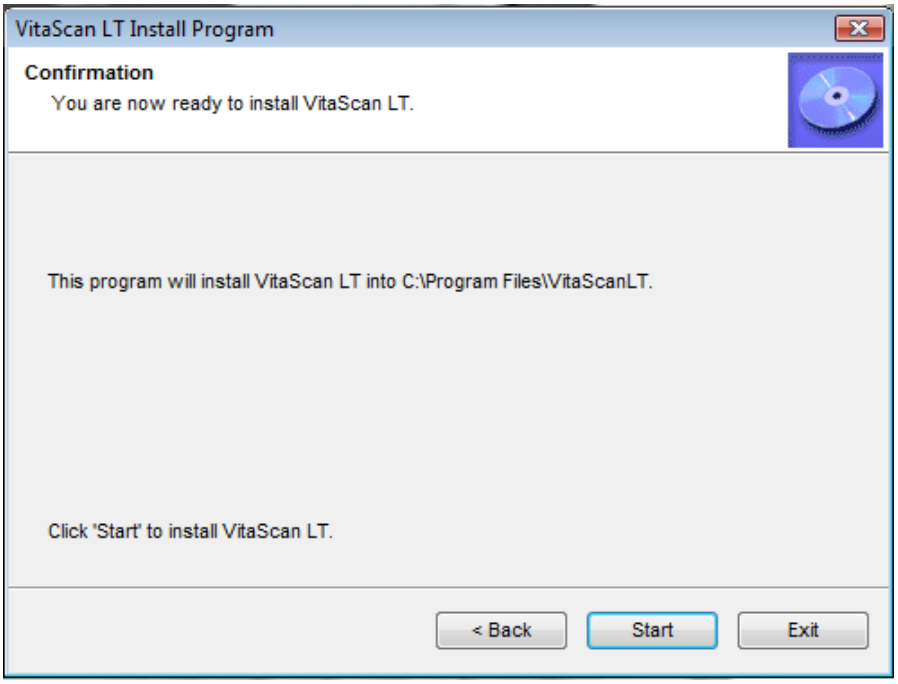
The “Next” button will get enabled when user chooses to accept the license agreement terms and conditions.


VitaScan LT Install Program
License
Please read the license agreement below.
Please read the license agreement below and select "I Agree" if you agree with its terms and conditions.
END USER LICENSE AGREEMENT
Copyright © 2005 - 2010 by Vitacon AS.
All rights reserved.
License
By using the enclosed program and/or installing the files from the original disks to your hard drive, you are agreeing to become bound by the terms of this agreement. If you do not agree to the terms of this agreement, uninstall all software and return all materials in
I agree with the above terms and conditions
I do not agree
< Back
Next >
Exit

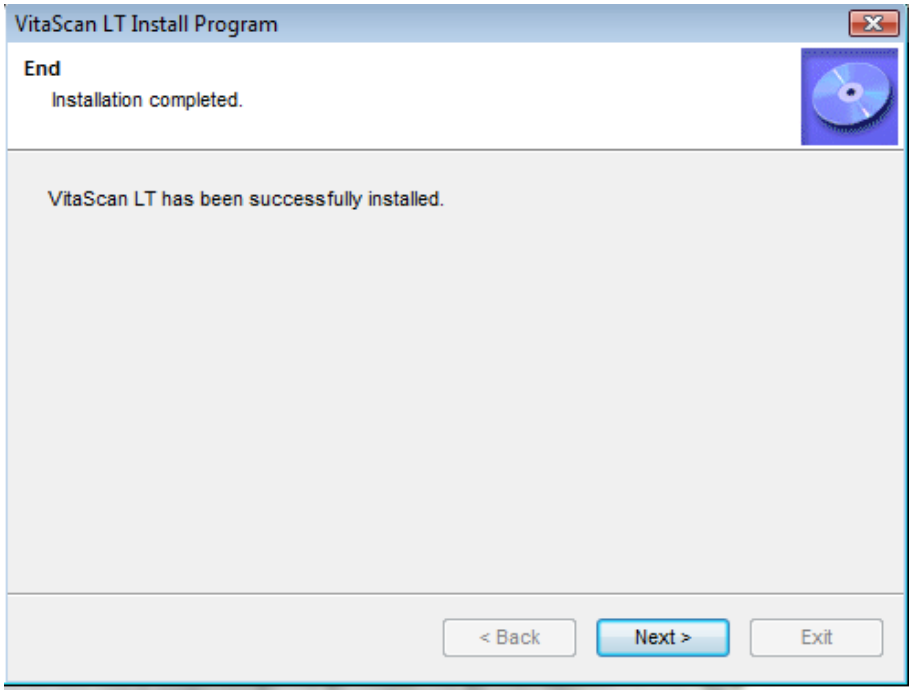
- Press Next, (It is recommended to install in the default directory)



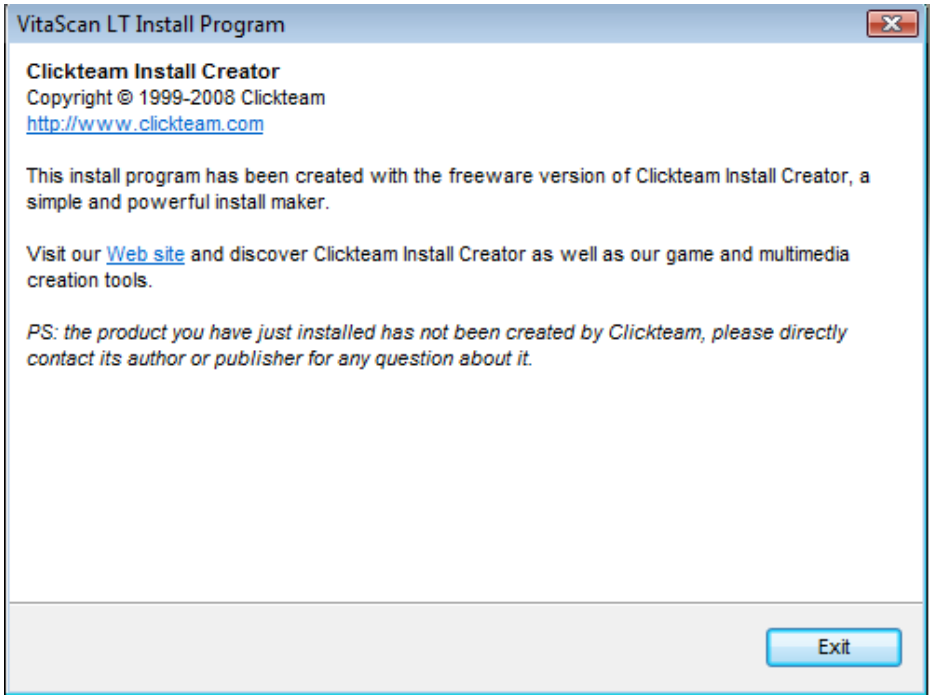
- Press Start.


VitaScan LT Install Program
Confirmation
You are now ready to install VitaScan LT.
This program will install VitaScan LT into C:\Program Files\VitaScanLT.
Click 'Start' to install VitaScan LT.
< Back
Start
Exit

- Press Next.



- Finish the installation by pressing Exit.


VitaScan LT Install Program
Clickteam Install Creator
Copyright © 1999-2008 Clickteam
http://www.clickteam.com
This install program has been created with the freeware version of Clickteam Install Creator, a simple and powerful install maker.
Visit our Web site and discover Clickteam Install Creator as well as our game and multimedia creation tools.
PS: the product you have just installed has not been created by Clickteam, please directly contact its author or publisher for any question about it.
Exit

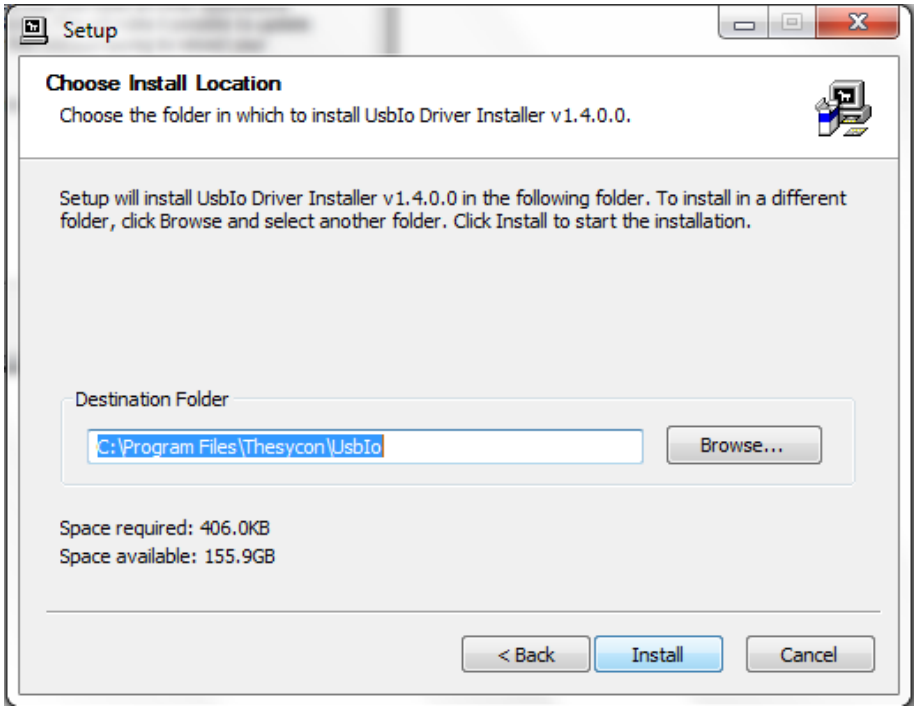
- After a successful installation a VitaScan LT icon will appear on your desktop.

USB driver Installation

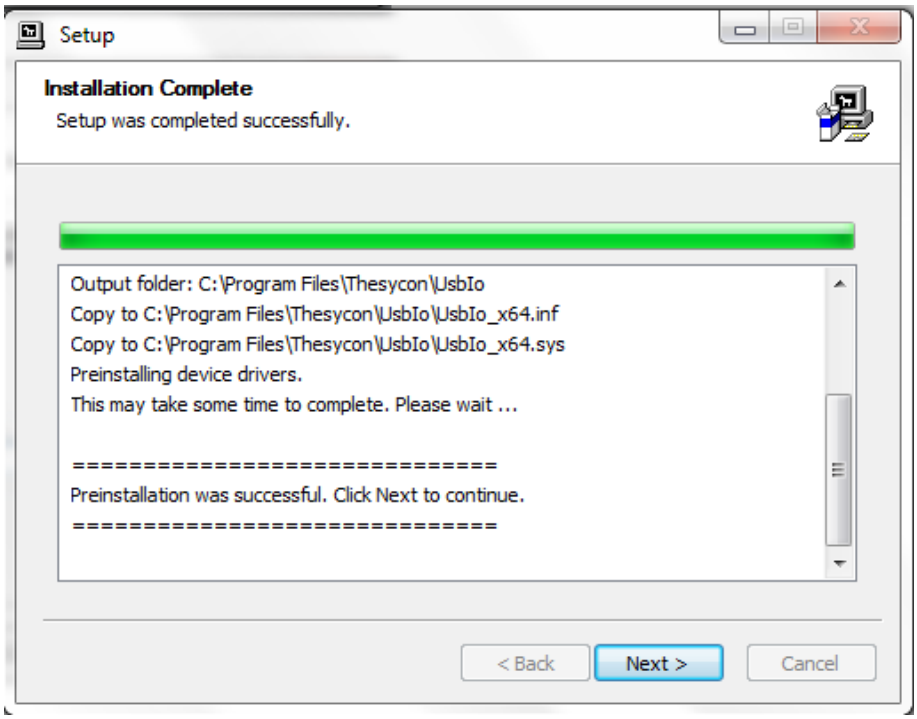
- First time VitaScan LT installation requires installation of USB driver for the VitaScan LT. Run SETUP.EXE located on the USB Memory stick in folder: Driver/setup.exe.
- Press Next (Note: the version indicated in the window is the installer version, not the USBIO version)

Setup
Welcome to the UsbIo Driver Installer v1.4.0.0 Setup Wizard
This wizard will guide you through the installation of UsbIo Driver Installer v1.4.0.0.
It is recommended that you close all other applications before starting Setup. This will make it possible to update relevant system files without having to reboot your computer.
Click Next to continue.
Next >
Cancel

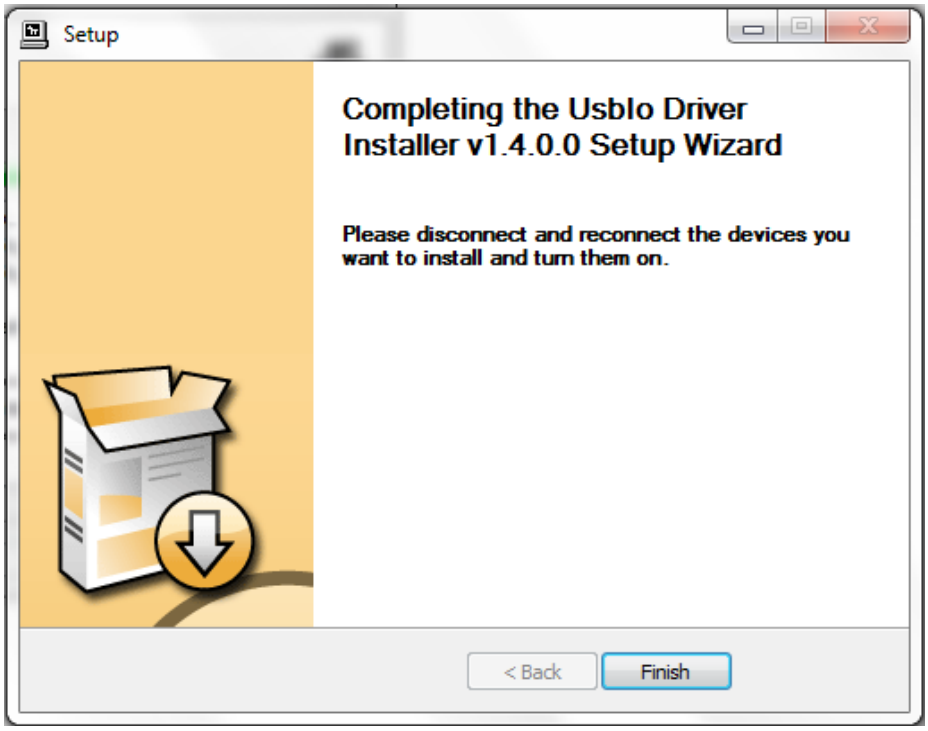
- Press Install


Setup
Choose Install Location
Choose the folder in which to install UsbIo Driver Installer v1.4.0.0.
Setup will install UsbIo Driver Installer v1.4.0.0 in the following folder. To install in a different folder, click Browse and select another folder. Click Install to start the installation.
Destination Folder
C:\Program Files\Thesycon\UsbIo
Browse...
Space required: 406.0KB
Space available: 155.9GB
< Back
Install
Cancel

- Press Next



- Finish the installation by pressing Finish.


Setup
Completing the Usblo Driver Installer v1.4.0.0 Setup Wizard
Please disconnect and reconnect the devices you want to install and turn them on.
< Back
Finish

- Connect the VitaScan LT probe to the computer to start the driver.

Note: if the PC has more than one USB port, please connect the probe to each different USB port while you are logged in as an “Administrator”. The USB driver will be automatically installed and the probe well recognized on whatever port it could be connected. The driver installation will not occur automatically if you are not logged in as an “Administrator”. The USB driver installation takes some time, please wait for Windows to display a successful installation message for each USB port.

User Guide

This section illustrates different features of the VitaScan LT PC Software application and guides the user through the application.

This application interacts with VitaScan LT Probe, Vitascan LT, for data acquisition.

The Application displays real time images to the user to locate bladder.
Once the scan is completed, the user can save the scanned images with patient information.

Ultrasound Bladder Monitor Application Software is developed to work on Windows XP/ Windows Vista/ Windows 7 operating system.

PC Software Application Key Features

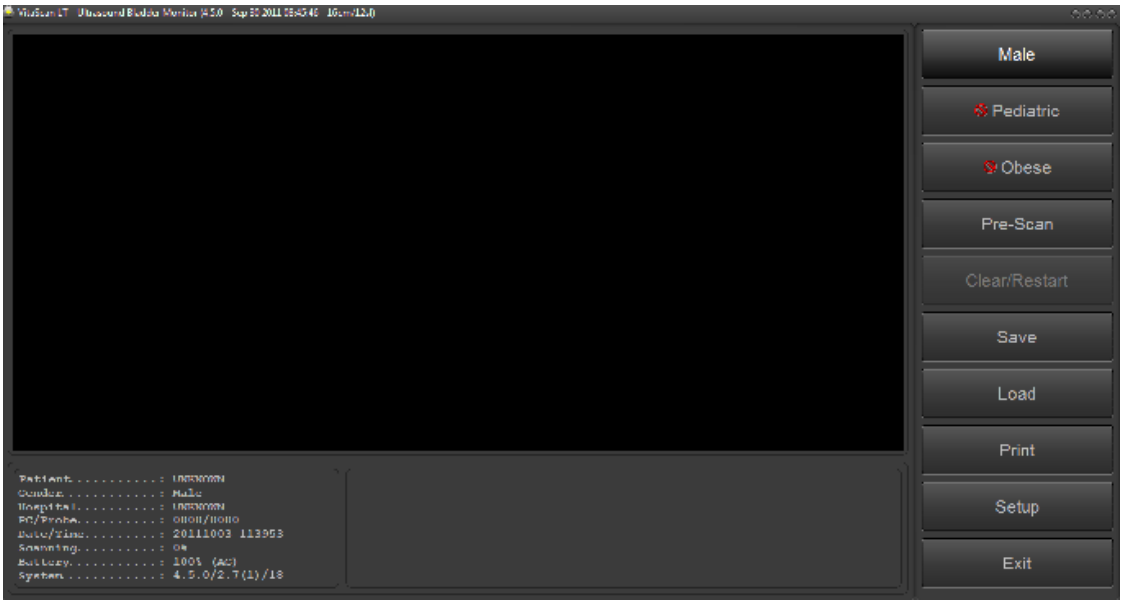
- Manage patient scan image data
- Displaying images of patient's scans, along with calculated urine volume
- Printable Report for a patient data
- Compatibility with Windows XP/ Windows Vista/ Windows 7 Operating Systems
- Rich Graphical User Interface and easy navigation
- VitaScan LT is configured to work for "No. Of Sectors To Scan" = 6, 12 or 24.

Application Features

- Pre-Scan image
- Scanned images
- Includes patient information with scanned images

Run VitaScan LT application

- Make sure the VitaScan LT probe is inserted in the computer port.
- Press the VitaScan LT Icon on your Desktop to start the application.

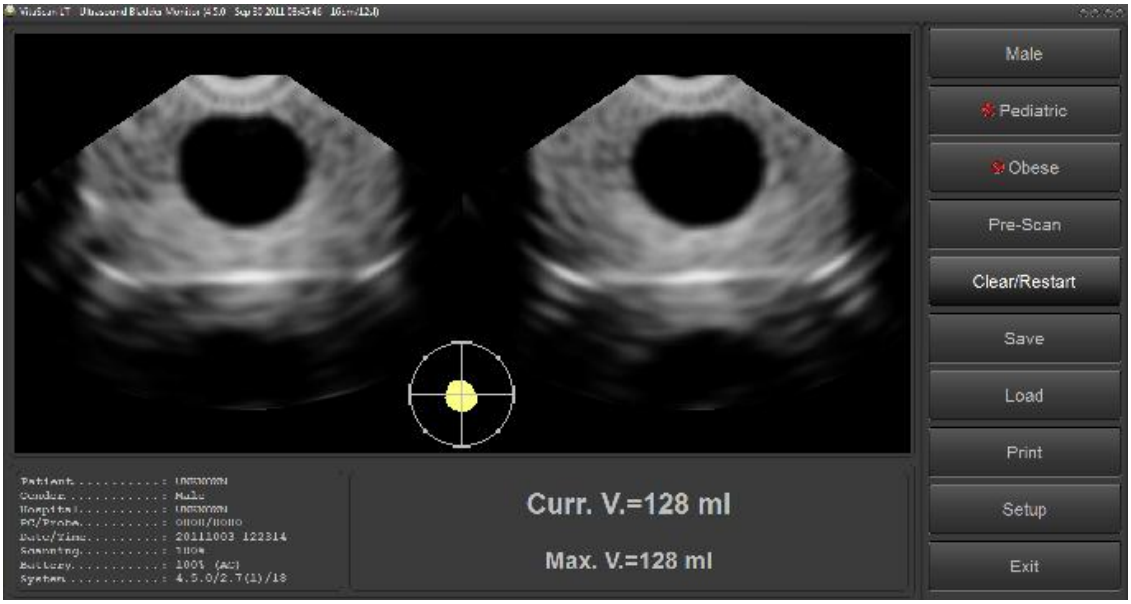


- Before scanning select Setup to insert User information, PC serial number, VitaScan LT information, and language. Number of scans for each measurement may be set to 6, 12 or 24. 12 scans is the default value.

- Pre-Scan is the first step, used to locate the bladder. Before starting the Pre-Scan, select the correct Gender, Pediatric and the Obese setting. By default, on power up, the gender will be "**Male**" and **Pediatric** - and **Obese** setting will be set to OFF.
- Press the "**Male**" button to change to "**Female**" setting.
- Press the "**Pediatric**" button to select pediatric setting. The max detection depth changes from 16 cm to 10 cm. The bladdersize will increase in the image. NOTE: This may take a few seconds.
- Press the "**Obese**" button to select obese setting. The max depth changes from 16 cm to 23 cm. The bladder can now be detected a further distance from the VitaScan LT probe. NOTE: This may take a few seconds.
- Press "**Pre-Scan**", this gives a real-time image of the bladder on the display. Use Pre-Scan to locate the bladder and aim the VitaScan LT directly above the bladder.

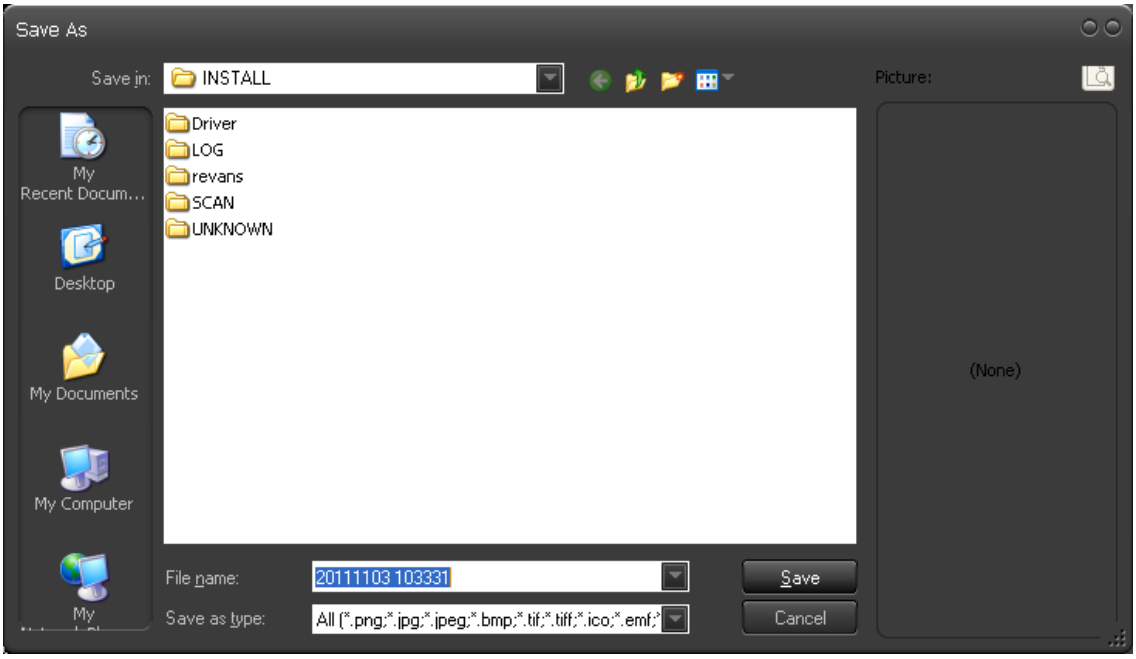
- When you have located the bladder, as in the picture above, press "Scan" to start scanning. NOTE: Do not move the VitaScan LT probe until scanning is 100% done.

- The results will appear as shown below. The left picture shows the horizontal scan, and the right picture shows the vertical scan. The lower cross hair picture shows the top view of the bladder in yellow.



- "Curr. V" shows the volume from the current scan. "Max. V" shows the maximum volume from multiple measurements. "ReScan please" shows when measurements are incorrect. **Clear/Restart** button will clear the screen and measurements. Use Clear/Reset button before scanning another patient.

- The result can be saved by pressing "**Save**". This will generate an exact image of what you see, including patient information and the volume result. The default name for a saved file is a timestamp which will have the form "20100108 094853". This means the scan was done on the Date: 2010/Jan/08 Time: 09:48:53. You may change this to another name, if desired.



- The result can also be printed by pressing print. It will give you the option to select a printer and chose if you want to print the picture in a landscape or normal orientation.

- To load an old scan, press “**load**” and select the scan you want to see. It will load the picture from the hard disk.

- To exit the application press “Exit” and “Yes”.

Scanning on Vitacon Phantom

- Before scanning on a Phantom enable the “**Phantom**” box under “**Setup**”. The Phantom box is disabled as a default setting. I.e. the Phantom box will be turned off when “**Setup**” is selected or the VitaScan LT application is started.

Other settings

- Enter Password 1234 to open other settings.

- Disable PreScan Timeout: Disables the 2 min. PreScan timeout
- Enable Data Logging: Enables automatic data logging of measurements. Data is stored with a timestamp in the folder c:\programfiles\VitaScanLT\INSTALL\LOG\SCAN. This option is normally only used for investigation of problems associated with image data.

Application – Troubleshooting

.

- Installation message: Driver not found
  - Uninstall driver
  - Open “Control Panel
  - Select ”User Accounts”
  - Select “Change Settings”
  - Drag the selection bar down to “No Warning”
  - Restart the computer
  - Re-install the driver

- Device should be configured before running the application.
  - In case of Windows XP OS, the USB driver needs to be configured before the application start.

- Application log file and Scan folder images are not getting generated in Windows Vista OS.
  - The log-in user should have access rights to the application folders, or should have administrator rights to the folders.

- Scanbutton is deactivated.
  - Press Clear/Restart button, or reset the VitaScan LT by removing USB connection for a few seconds and insert again.
  - Turn off “Power Saving Mode”. Set Power Plan of the computer to “High Performance”.

- Incorrect detection of bladder.
  - Insufficient battery capacity, connect to external safe power supply.
  - Turn OFF “Power Saving Mode”. Set Power Plan to “High Performance”.
  - Turn OFF “Wireless network connection” on your computer settings.
  - Turn OFF “Bluetooth connection” on your computer settings.
  - Stop “antivirus program” on your computer settings. – if applicable.

- ReScan please.
  - Incorrect detection of bladder. Apply more gel on the Scanhead/abdomen, and angle the Scanhead below the pubic bone. Verify that the bladder is placed over the center of the Bladder.

Warranty and Disclaimer Information

Warranty:
Vitacon warrants the VitaScan LT against defects in material and workmanship of one (1) year from the date of purchase from Vitacon. This warranty is given only to the original purchaser of the VitaScan LT instrument.

Pursuant to this warranty, a service center authorized by Vitacon will repair or replace products which prove to be defective during the warranty period.

This warranty does not cover equipment sold as used.

This warranty does not apply if the product has been damaged by misuse or as the result or service or modification by anyone other than a service center authorized by Vitacon. The instrument shall be used in accordance with the instructions contained in this manual.

Consumable items shall be used in conformance with VitaScan product specifications. Consumable items are not covered under this warranty.

Warranty conditions may differ in some countries. Contact your local distributor for warranty terms.

Warranty extensions are available. For more information, please talk to your local Vitacon representative, or contact Vitacon using the contact information give in the manual.

Disclaimer of Additional Warranties:

There are no understandings, agreements, representations of warranties expressed or implied (including warranties of merchantability or fitness for a particular purpose) other than those set forth in the preceding warranty section. The contents of this manual do not constitute a warranty.

Some states disallow certain limitations on applied warranties. The purchaser, user and patient should consult state law if there is a question regarding this disclaimer.

The information, descriptions, recommendations and safety notations in this manual are based upon Vitacon experience and judgment, as of December 2011 with respect to the VitaScan LT. The contents of this manual should not be considered to be all inclusive or covering all contingencies.

The physician(s) at your institution directing the use of the VitaScan LT is responsible for keeping current with developments in the literature on bladder volume determination. Please direct any questions or problems concerning bladder volume measurement, the use of the instrument, or interpretation of data, to the responsible physician(s)

Service

The Information contained in this service manual is proprietary to the Vitacon. It is supplied solely for the convenience of our customers. It may be changed in whole or in part without the written notice.

This manual is not intended as support for any unauthorized servicing, disassembly, rebuilding, modification or resale of VitaScan LT by unauthorized third parties.

Introduction

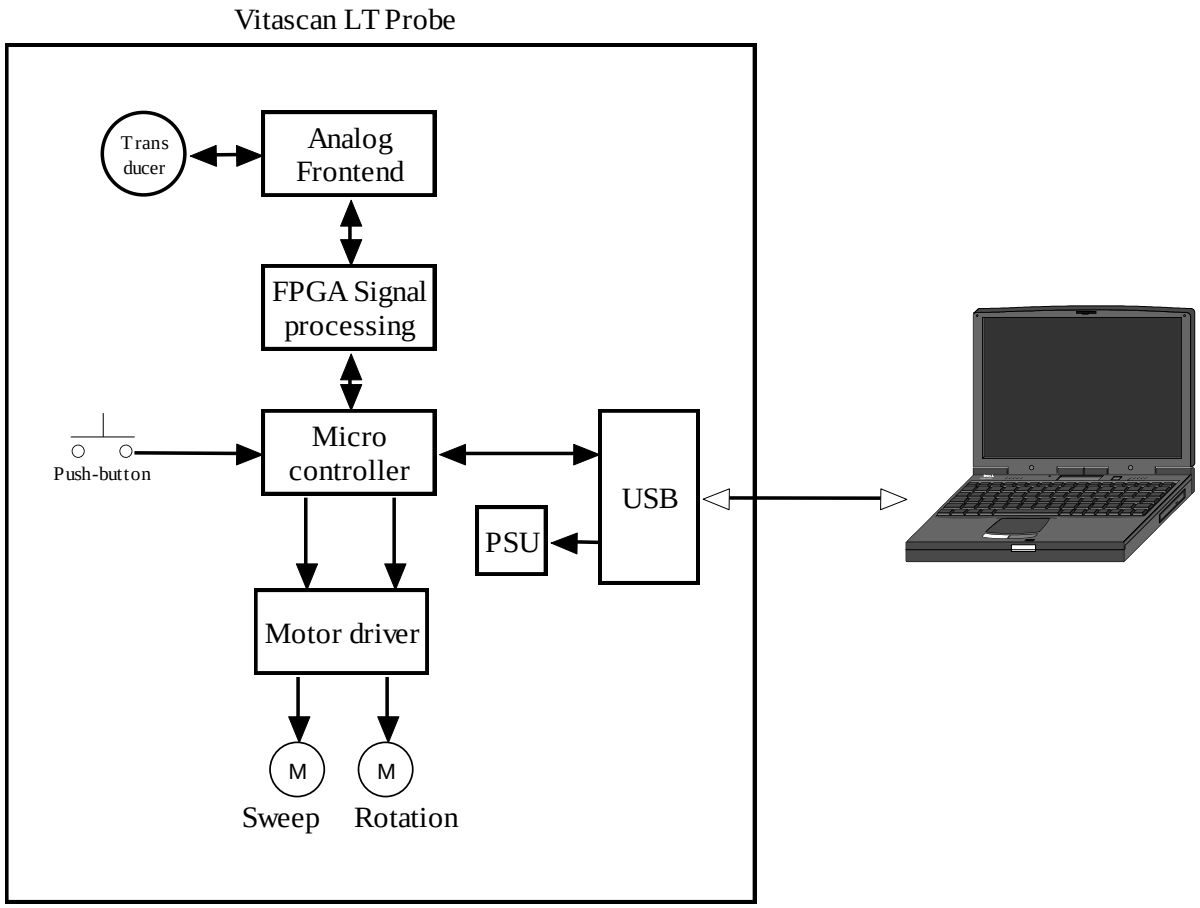
This section contains the IVBM VUFE technical specification and architectural design description. IVBM VUFE is the electronic module in the VitaScan LT bladder volume scanner. VitaScan LT is a 3-dimensional ultrasonic scanning device used to measure the bladder volume and quantity of urine remaining in the bladder; safely and comfortably through a non-invasive method.

The VitaScan LT probe consists of mechanics and electronics. The VitaScan LT contains the mechanical components needed to execute the 3 dimensional scanning of the bladder, and the electronics to obtain the ultrasound image needed to calculate the volume of urine in the bladder both pre and post void.

The VitaScan LT probe is attached to the computer via a USB connection, which also provides the necessary power to the probe. This document only covers the technical specification for the probe electronics, IVBM VUFE.

Overview

The drawing below shows an overview of the complete VitaScan LT bladder scanner system. All modules are physically located inside the VitaScan LT.



Block diagram for VitaScan LT Probe

Functional Description

The IVBM VUFE is a single element ultrasound scanner with the electronic module and scanning mechanics, designed to fit in a hand held scanner, having the following main functionality:

- USB communication interface for computer
- Ultrasound Pulse generator
- Ultrasound receiver and signal processing
- Motor control and positioning of the ultrasound transducer element

The module is realized in analog and digital hardware, FPGA configuration, and microcontroller firmware. The following are the main parts of the design:

- Microcontroller
- FPGA
- PSU
- USB
- Motor driver
- Analogue Receiver and transmitter

Microcontroller

The microcontroller is the master in the IVBM VUFE-module, controlling all functionality and safety. It is also a communication interface between the Probe and the computer. The microcontroller is a slave with respect to the computer, and will only communicate in response to a command from the computer.

Microcontroller states of operation:

Power up:

At normal power up, a self-test and initiation procedure will start. The FPGA configuration will be cleared and configuration must be downloaded from the computer before ultrasound acquisition may start. The transducer element positions will be initialized.

At power up with the push-button pressed, the module will enter “PROGRAM” mode, waiting for firmware upgrade via the USB connection. This is a maintenance function, and should only be used by trained service personnel.

Idle:

In Idle state, the module is waiting for a command from the computer or the pushbutton. The current consumption is reduced to an absolute minimum.

Pre-Scan:

In Pre-Scan mode, the module will move the transducer sweep-motor continuously between the end positions, and ultrasound data for one vector will be transmitted to the computer at each defined position. The rotation-motor is parked in the initial position. This will give the computer the possibility to present a “live” image of the bladder, making it possible to move the VitaScan LT to the correct position before making a Full-Scan with volume calculation.

Full-Scan:

In Full-Scan mode, the module will move the transducer sweep-motor from one end position to the other, transmitting ultrasound data for one vector to the computer at each defined position. The rotation motor will then move one step, and a new sweep will be performed. When the rotation motor has moved a total of 180 degrees, and the computer has received a number of vectors defining a set

FPGA:

The FPGA (Field Programmable Gate Array) is responsible for all signal-processing in the IVBM VUFE module.

The microcontroller configures the FPGA with “Bitstream” data and configuration data received by the computer.

The microcontroller initiates an “Ultrasound capture sequence” by a Trigger signal. The FPGA will generate an ultrasound pulse according to the configuration data, receive the echo, and send data for the vector to the microcontroller after signal processing.

PSU:

The PSU (power supply unit) in the IVBM-VUFE module get its input voltage from the USB-connection. The computer will provide all power needed by the IVBM-VUFE module, including motors and transducer that are driven from this module. The power consumption must be lower than the maximum rating of power to be provided by the computers USB port.

The PSU will provide 4 different voltages:

1.2V: FPGA
3.3V: Microcontroller,
5.0V: Analog receiver, Motor driver logic
Motor: HW-programmable voltage for the motors to be used

USB:

The USB controller is an integral part of the microcontroller.

The IVBM-VUFE USB will be the SLAVE, and the computer will be MASTER. Implementation of the USB firmware follows the USB 2.0 standard.

Motor driver:

The motor driver is designed for running Stepper-motors, and consists of three parts:

- A HW part that will transform logical control signals into currents driving the motors.
- A SW part in the microcontroller that will keep track of position of each motor, and generate logical control signals to move the motors to correct positions dependent on operating mode.
- A HW HAL-sensor and magnet to be used as a reference to calibrate sweep-motor position.

The motor driver is designed to support Full-step, Half-step and Micro-step modes, but for maximum motor-torque the Full-Step mode is used. The motor supply voltage is made HW-programmable to support different step-motors.

Analog Receiver and Transmitter:

The transmitter is a bipolar "square-wave" pulse transmitter. The voltage level is settable to tree levels by software/configuration data control. The waveform is controlled by a sequence generator in the FPGA. The input signal from the transducer is attenuated by a t/r-switch during the pulse transmit period. The t/r-switch is controlled by a sequencer in the FPGA. The receiving signal is amplified by a TGC-amplifier chain. The gain control signal is set by an analog ramp signal, controlled from the FPGA. The amplified analog receive signal is low-pass filtered by a passive L-C filter before it is fed to the A/D-converter. The A/D converter is clocked from the FPGA. Resolution is 12 bits, and sampling speed is 12.5MHz. The parallel output data is fed to the FPGA for further digital processing.

Safety Mechanisms:

The following safety mechanisms are implemented in the IVBM VUFE module:

TX-Voltage and Input voltage monitoring

Software Watchdog:

The microcontroller is supervising the voltages in the “main loop” for maximum safety, and a watchdog is supervising the microcontroller program execution.

In case of a SW/HW error that causes abnormal program execution, a HW-reset condition will occur and the High Voltage will be disabled. The HW has a measurement circuit allowing the microcontroller to measure the High Voltage and the Input voltage.

The microcontroller will disable the TX Voltage if the voltage is out of the pre-defined range (+-10% of set value), and an error will be sent to the computer.

If the Input voltage is reaches the minimum value (4.2V), an error message will be sent to the computer.

If the input voltage is too low to drive the IVBM VUFE, a HW-reset condition will occur and the High Voltage will be disabled.

Vitacon. will upon request make available other technical documentation which will assist qualified technical personnel to repair the equipment. Repair should be performed only by Vitacon authorized service organization.

Copyright 2012 by Vitacon. All rights reserved.